

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|------------------------------|---|----------------------------|
| KONINKLIJKE PHILIPS N.V. and |) | |
| IP2IPO INNOVATIONS, LTD., |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | C.A. No. _____ |
| |) | |
| BOSTON SCIENTIFIC |) | JURY TRIAL DEMANDED |
| CORPORATION, |) | |
| |) | |
| Defendant. |) | |

**COMPLAINT FOR PATENT INFRINGEMENT
AND DEMAND FOR JURY TRIAL**

Koninklijke Philips N.V. (“Philips”) and IP2IPO Innovations, Ltd. (“IP2IPO”) (collectively, “Plaintiffs”), by way of this Complaint for Patent Infringement under 35 U.S.C. § 271 against Defendant Boston Scientific Corporation (“BSC” or “Defendant”), state on information and belief as follows:

THE PARTIES

1. Plaintiff Philips is a corporation duly organized and existing under the laws of the Netherlands. Its principal place of business is High Tech Campus 52, 5656 AG Eindhoven, the Netherlands.

2. Plaintiff IP2IPO has a place of business at the Walbrook Building, 25 Walbrook, London, EC4N 8AF.

3. Plaintiff IP2IPO is a wholly owned subsidiary of IP Group, PLC, which is a public limited company duly organized and existing under the laws of

the United Kingdom, with a place of business at the Walbrook Building, 25 Walbrook, London, EC4N 8AF.

4. BSC is a corporation duly organized and existing under the laws of the State of Delaware with its principal place of business at 300 Boston Scientific Way, Marlborough, Massachusetts 01752.

5. BSC is in the business of, *inter alia*, making, using, selling, offering for sale, and/or importing medical devices throughout the United States.

JURISDICTION AND VENUE

6. Plaintiffs incorporate each of preceding paragraphs 1–5 of this Complaint as if fully set forth and restated herein.

7. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over BSC. BSC is incorporated in Delaware and resides in this District for purposes of 28 U.S.C. §§ 1391 and 1400. BSC has systematic and continuous contacts in this judicial district, regularly transacts business within this district, and regularly avails itself of the benefits of this District.

9. Venue is proper against BSC under 28 U.S.C. §§ 1391 and 1400(b) because BSC is incorporated in and resides in Delaware and in this District.

THE PATENTS-IN-SUIT

10. Plaintiffs incorporate each of preceding paragraphs 1–9 of this Complaint as if fully set forth and restated herein.

U.S. Patent 7,134,994

11. On November 14, 2006, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,134,994 (“the ’994 patent”), titled “Multipurpose Host System for Invasive Cardiovascular Diagnostic Measurement Acquisition and Display.” A true and correct copy of the ’994 patent is attached as Exhibit A.

12. Philips is the assignee and owner of the ’994 patent.

U.S. Patent 8,636,659

13. On January 28, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,636,659 (“the ’659 patent”), titled “Multipurpose Host System for Invasive Cardiovascular Diagnostic Measurement Acquisition and Display.” A true and correct copy of the ’659 patent is attached as Exhibit B.

14. Philips is the assignee and owner of the ’659 patent.

U.S. Patent 9,392,979

15. On July 19, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,392,979 (“the ’979 patent”), titled “Multipurpose Host System for Invasive Cardiovascular Diagnostic Measurement Acquisition and Display.” A true and correct copy of the ’979 patent is attached as Exhibit C.

16. Philips is the assignee and owner of the ’979 patent.

U.S. Patent 9,364,153

17. On June 14, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,364,153 (“the ’153 patent”), titled “Devices, Systems, and Methods and Associated Display Screens for Assessment of Vessels.” A true and correct copy of the ’153 patent is attached as Exhibit D.

18. Philips is the assignee and owner of the ’153 patent.

U.S. Patent 9,974,443

19. On May 22, 2018, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,974,443 (“the ’443 patent”), titled “Devices, Systems, and Methods and Associated Display Screens for Assessment of Vessels.” A true and correct copy of the ’443 patent is attached as Exhibit E.

20. Philips is the assignee and owner of the ’443 patent.

U.S. Patent 9,775,524

21. On October 3, 2017, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,775,524 (“the ’524 patent”), titled “Apparatus and Method of Assessing a Narrowing in a Fluid Filled Tube.” A true and correct copy of the ’524 patent is attached as Exhibit F.

22. IP2IPO is the assignee and owner of the ’524 patent.

23. Philips is an exclusive licensee of the ’524 patent in the field of coronary pulse pressure waveform analysis.

BACKGROUND

24. Plaintiffs incorporate each of preceding paragraphs 1–23 of this Complaint as if fully set forth and restated herein.

25. Philips is a leading designer and supplier of medical devices for use in percutaneous coronary intervention (“PCI”) procedures. Philips’ integrated cardiology ecosystem of data and devices work together to help doctors and medical professionals to provide efficient and effective cardiac care in the most appropriate setting. Working in partnership with health systems and healthcare professionals in their financial and operational goals, Philips drives innovation and enables tailored care transformations in a value-driven era.

26. IP2IPO is a subsidiary of IP Group, which focuses on evolving great ideas, mainly from its partner universities, into world-changing businesses. IP

Group has long-term partnerships with many leading universities that develop ideas and inventions that fuel innovation.

THE ACCUSED PRODUCTS

27. Plaintiffs incorporate each of preceding paragraphs 1–26 of this Complaint as if fully set forth and restated herein.

28. The Accused Products include Defendant’s interventional cardiology or PCI host systems (e.g., Defendant’s POLARIS Multi-Modality Guidance System, including the POLARIS Cart System, and the POLARIS Integrated System); intravascular measurement devices (e.g., Defendant’s COMET Pressure Guidewire or OPTICROSS catheter); catheters (e.g., Defendant’s CONVEY, MACH and RUNWAY Guide Catheters and Defendant’s EXPO and IMPULSE Diagnostic Catheters); and Diastolic Hyperemia-Free Ratio (“DFR”) hardware and/or software.

29. Defendant’s website describes its POLARIS Multi-Modality Guidance System as offering a “portfolio for coronary physiology and IVUS (intravascular ultrasound).” <https://www.bostonscientific.com/en-IN/products/imaging-systems/polaris.html> (last accessed Oct. 30, 2020). The image below shows Defendant’s POLARIS Multi-Modality Guidance System in the cart configuration:



Figure 1: POLARIS Cart Configuration

30. Defendant provides this sample image of the POLARIS interface on a YouTube video

https://www.youtube.com/watch?v=H_CxGAnaWi0&feature=emb_title (last accessed Oct. 30, 2020):



Figure 2: POLARIS Sample Interface

31. Defendant's website describes its COMET pressure guidewire as a "workhorse pressure guidewire – now with FFR and DFR."

<https://www.bostonscientific.com/en-US/products/ffr-ivus-systems/polaris.html>
(last accessed Oct. 30, 2020).

32. Defendant's website describes its OPTICROSS catheter as a "Coronary Imaging Catheter" in its "FFR & IVUS Systems" product tab.
<https://www.bostonscientific.com/en-US/products/ffr-ivus-systems/complex-pci-ivus-catheter.html> (last accessed Oct. 30, 2020).

NATURE OF THE ACTION

33. Plaintiffs incorporate each of preceding paragraphs 1–32 of this Complaint as if fully set forth and restated herein.

34. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant for infringement of the '994, '659, '979, '153, '443, and '524 patents (collectively, "patents-in-suit"). The patents-in-suit relate to interventional cardiology or PCI.

35. As discussed in greater detail below, Defendant has infringed and continues to infringe one or more claims of each of the patents-in-suit literally and/or under the doctrine of equivalents by making, using, selling, offering for sale, and/or importing the Accused Products, and all reasonably similar products.

36. As discussed in greater detail below, Defendant indirectly infringes the patents-in-suit by inducing its customers to directly infringe one or more claims of the patents-in-suit. With knowledge that its customers directly infringe the patents-in-suit when at least using and/or making one or more of the Accused Products as intended, and by intentionally encouraging such acts, Defendant is liable for induced infringement under 35 U.S.C. § 271(b).

37. As discussed in greater detail below, Defendant indirectly infringes the patents-in-suit by contributing to the direct infringement of one or more claims of the patents-in-suit by its customers. Defendant knows the Accused Products are especially made or adapted for use by its customers in a manner that directly

infringe the patents-in-suit under 35 U.S.C. § 271(a). Because the Accused Products also are not staple articles of commerce and are not suitable for substantial noninfringing uses, Defendant is liable for contributory infringement under 35 U.S.C. § 271(c).

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '994 Patent

38. Plaintiffs incorporate each of preceding paragraphs 1–37 of this Complaint as if fully set forth and restated herein.

39. In violation of 35 U.S.C. § 271(a), Defendant has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '994 patent, including at least claim 1, by making, using, selling, offering for sale, and/or importing into the United States one or more of the Accused Products.

40. The Polaris Multi-Modality Guidance System is a multipurpose host system for invasive cardiovascular diagnostic measurement acquisition and display incorporating a component based arrangement, the system comprising: an external input signal bus interface for receiving data arising from cardiovascular diagnostic measurement sensors (e.g., interface for an OPTICROSS catheter); a plurality of measurement processing components, that operate at a user mode level in the multipurpose host system, for facilitating data of particular sensor types and rendering diagnostic measurement parameter values according to the received data (e.g., processors and software in the Polaris Cart System or Polaris Integrated System); a multi-mode graphical user interface host comprising diagnostic measurement user interfaces including display components corresponding to data output rendered by specific ones of the plurality of measurement processing components (e.g., the screen on the Polaris Cart System or Polaris Integrated

System); and one or more kernel mode drivers that extract processed sensor data from a peripheral interface card providing a hardware interface for one or more invasive diagnostic measurement devices (e.g., Polaris drivers extracting data related to a COMET pressure guidewire or OPTICROSS catheter).

41. Defendant has been on notice of the '994 patent since at least as early as the service of this Complaint. Defendant's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after service of the Complaint, would be with Defendant's knowledge of the '994 patent, knowledge of infringement of the '994 patent, intent to encourage others (e.g., its customers) to infringe the '994 patent through the Accused Products, and knowledge that Defendant's encouraging acts actually result in direct infringement of the '994 patent by Defendant's customers.

42. Defendant had knowledge of the '994 patent or was willfully blind to the patented features of the '994 patent before the filing and service date of this Complaint. Defendant at least had constructive notice of the '994 patent under 35 U.S.C. § 287.

43. Defendant, in violation of 35 U.S.C. § 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents at least claim 1 of the '994 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '994 patent. Defendant's customers who use, make, sell, offer for sale, and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 1 of the '994 patent, in violation of 35 U.S.C. § 271(a).

44. Defendant actively instructs, encourages, and/or aids such infringement through various activities, including by instructing and training medical professionals to use one or more of the Accused Products in a manner

consistent with one or more claims of the '994 patent, through descriptions on Defendant's website and through product documentation.

45. Defendant, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 1 of the '994 patent by contributing to their customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '994 patent. Defendant's customers who make, use, sell, offer for sale, and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 1 of the '994 patent, in violation of 35 U.S.C. § 271(a).

46. Defendant contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '994 patent.

47. The Accused Products are not staple articles of commerce.

48. The Accused Products are not suitable for substantial noninfringing uses.

49. Philips has complied with 35 U.S.C. § 287 for the '994 patent.

50. Philips has been injured by Defendant's infringement of the '994 patent and will suffer irreparable harm unless Defendant is enjoined from infringing the '994 patent.

COUNT II FOR PATENT INFRINGEMENT

Infringement of the '659 Patent

51. Plaintiffs incorporate each of preceding paragraphs 1–50 of this Complaint as if fully set forth and restated herein.

52. In violation of 35 U.S.C. § 271(a), Defendant has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '659 patent, including at least claim 13, by making, using, selling, offering for sale, and/or importing into the United States one or more of the Accused Products.

53. The Polaris Multi-Modality Guidance System is a multi-purpose host system for use in intravascular procedures, comprising: a user interface having at least one user input device and a display (e.g., a touch screen or handheld control device and a monitor screen in the Polaris Cart System or Polaris Integrated System); a processing system having a plurality of separate processing components, wherein each of the plurality of processing components are configured to process data related to an intravascular parameter that is different than intravascular parameters of the other of the plurality of processing components such that the plurality of processing components are configured to process a plurality of intravascular parameters independently of one another (e.g., processors and software in the Polaris Cart System or Polaris Integrated System); and an interface in communication with the processing system, the interface configured to receive data from a plurality of intravascular sensing components, wherein the data received from each of the plurality of intravascular sensing components includes data related to one of the plurality of intravascular parameters and wherein the interface is configured to communicate the data related to one of the plurality of intravascular parameters to the processing system (e.g., a computer port in communication with a COMET pressure guidewire or OPTICROSS catheter); wherein the multi-purpose host system is configured to control operation of at least one of the plurality of intravascular sensing components in response to input received from the at least one user input device of the user interface of the multi-purpose host system and configured to display at least a portion of the data

received from the plurality of intravascular sensing components on the user interface of the multi-purpose host system (e.g., the Polaris controls a COMET pressure guidewire or OPTICROSS catheter in response to input received from a touchscreen or handheld control device and displaying a portion of the data received on a monitor screen of the Polaris Cart System or Polaris Integrated System).

54. Defendant has been on notice of the '659 patent since at least as early as the service of this Complaint. Defendant's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after service of the Complaint, would be with Defendant's knowledge of the '659 patent, knowledge of infringement of the '659 patent, intent to encourage others (e.g., its customers) to infringe the '659 patent through the Accused Products, and knowledge that Defendant's encouraging acts actually result in direct infringement of the '659 patent by Defendant's customers.

55. Defendant had knowledge of the '659 patent or was willfully blind to the patented features of the '659 patent before the filing and service date of this Complaint. Defendant at least had constructive notice of the '659 patent under 35 U.S.C. § 287.

56. Defendant, in violation of 35 U.S.C. § 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents at least claim 13 of the '659 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '659 patent. Defendant's customers who use, make, sell, offer for sale and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 13 of the '659 patent, in violation of 35 U.S.C. § 271(a).

57. Defendant actively instructs, encourages, and/or aids such infringement through various activities, including by training medical professionals to use one or more of the Accused Products in a manner consistent with one or more claims of the '659 patent, through descriptions on its website and through product documentation.

58. Defendant, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 13 of the '659 patent by contributing to their customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '659 patent. Defendant's customers who make, use, sell, offer for sale, and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 13 of the '659 patent, in violation of 35 U.S.C. § 271(a).

59. Defendant contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '659 patent.

60. The Accused Products are not staple articles of commerce.

61. The Accused Products are not suitable for substantial noninfringing uses.

62. Philips has complied with 35 U.S.C. § 287 for the '659 patent.

63. Philips has been injured by Defendant's infringement of the '659 patent and will suffer irreparable harm unless Defendant is enjoined from infringing the '659 patent.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the '979 Patent

64. Plaintiffs incorporate each of preceding paragraphs 1–63 of this Complaint as if fully set forth and restated herein.

65. In violation of 35 U.S.C. § 271(a), Defendant has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '979 patent, including at least claim 12, by making, using, selling, offering for sale, and/or importing into the United States one or more of the Accused Products.

66. The Polaris Multi-Modality Guidance System is a multi-purpose host system for use in intravascular procedures, comprising: a user interface having at least one user input device (e.g., a touch screen or handheld control device) and a display (e.g, the screen on the Polaris Cart or Polaris Intergrated system); at least one intravascular device including a plurality of intravascular sensing components (e.g., a COMET pressure guidewire or OPTICROSS catheter); and a processing system in communication with the user interface and the at least one intravascular device (e.g., processors or software in communication with a touch screen or a handheld control device and a COMET pressure guidewire or OPTICROSS catheter), the processing system configured to: control, in response to an input to the at least one user input device of the user interface, operation of the plurality of intravascular sensing components via a component in communication with the processing system and the plurality of intravascular sensing components (e.g., controlling the operation of a COMET pressure guidewire or OPTICROSS catheter with a touchscreen or handheld control device); receive data related to a plurality of intravascular parameters from the plurality of intravascular sensing components (e.g., via a port); process the data related to the plurality of intravascular parameters to produce visual representations of each of the plurality of

intravascular parameters for display on the display of the user interface (e.g., with Polaris processors or software); and output at least one of the visual representations of the plurality of intravascular parameters to the display of the user interface based on a selected display mode (e.g., on the monitor display of the Polaris Cart System or Polaris Integrated System); wherein the processing system is configured to switch the selected display mode in response to an input to the at least one user input device of the user interface (e.g., via a touch screen or handheld control device).

67. Defendant has been on notice of the '979 patent since at least as early as the service of this Complaint. Defendant's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after service of the Complaint, would be with Defendant's knowledge of the '979 patent, knowledge of infringement of the '979 patent, intent to encourage others (e.g., its customers) to infringe the '979 patent through the Accused Products, and knowledge that Defendant's encouraging acts actually result in direct infringement of the '979 patent by Defendant's customers.

68. Defendant had knowledge of the '979 patent or was willfully blind to the patented features of the '979 patent before the filing and service date of this Complaint. Defendant at least had constructive notice of the '979 patent under 35 U.S.C. § 287.

69. Defendant, in violation of 35 U.S.C. § 271(b), has indirectly infringed and continue to literally and/or under the doctrine of equivalents indirectly infringe at least claim 12 of the '979 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '979 patent. Defendant's customers who use, make, sell, offer for sale and/or import the

Accused Products in accordance with Defendant's instructions infringe at least claim 12 of the '979 patent, in violation of 35 U.S.C. § 271(a).

70. Defendant actively instructs, encourages, and/or aids such infringement through various activities, including by training medical professionals to use one or more of the Accused Products in a manner consistent with one or more claims of the '979 patent, through descriptions on its website and through product documentation.

71. Defendant, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 12 of the '979 patent by contributing to their customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '979 patent. Defendant's customers who make, use, sell, offer for sale, and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 12 of the '979 patent, in violation of 35 U.S.C. § 271(a).

72. Defendant contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '979 patent.

73. The Accused Products are not staple articles of commerce.

74. The Accused Products are not suitable for substantial noninfringing uses.

75. Philips has complied with 35 U.S.C. § 287 for the '979 patent.

76. Philips has been injured by Defendant's infringement of the '979 patent and will suffer irreparable harm unless Defendant is enjoined from infringing the '979 patent.

COUNT IV FOR PATENT INFRINGEMENT

Infringement of the '153 Patent

77. Plaintiffs incorporate each of preceding paragraphs 1–76 of this Complaint as if fully set forth and restated herein.

78. In violation of 35 U.S.C. § 271(a), Defendant has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '153 patent, including at least claim 18, by making, using, selling, offering for sale, and/or importing into the United States one or more of the Accused Products.

79. The Polaris Multi-Modality Guidance System is a system for evaluating a vessel of a patient, comprising: a processing system in communication with first and second instruments sized and shaped for introduction into the vessel of the patient (e.g., Polaris processors or software in communication with a COMET pressure guidewire and CONVEY, MACH or RUNWAY Guide Catheters or EXPO or IMPULSE Diagnostic Catheters), the processing unit configured to: obtain pressure measurements from the first and second instruments while the second instrument is moved longitudinally through the vessel of the patient from a first position to a second position while the first instrument is maintained in a fixed longitudinal position with respect to the vessel (e.g., while a COMET pressure guidewire is moved longitudinally through the vessel while a CONVEY, MACH or RUNWAY Guide Catheter or EXPO or IMPULSE Diagnostic Catheter remains stationary); and output a screen display having visual representations of the pressure measurements obtained by the first and second instruments on a display in communication with the processing system, the screen display including (e.g., on a monitor display of a Polaris Cart System or Polaris Integrated System): a graphical display of a pressure ratio of the obtained pressure measurements (e.g., a graphical display of DFR); and at least a portion of a

pressure waveform of the obtained pressure measurements identifying a diagnostic period utilized in calculating the pressure ratio (e.g., by implementing the criteria for DFR).

80. Defendant has been on notice of the '153 patent since at least as early as the service of this Complaint. Defendant's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after service of the Complaint, would be with Defendant's knowledge of the '153 patent, knowledge of infringement of the '153 patent, intent to encourage others (e.g., its customers) to infringe the '153 patent through the Accused Products, and knowledge that Defendant's encouraging acts actually result in direct infringement of the '153 patent by Defendant's customers.

81. Defendant had knowledge of the '153 patent or was willfully blind to the patented features of the '153 patent before the filing and service date of this Complaint. Defendant at least had constructive notice of the '153 patent under 35 U.S.C. § 287.

82. Defendant, in violation of 35 U.S.C. § 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 18 of the '153 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '153 patent. Defendant's customers who use, make, sell, offer for sale and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 18 of the '153 patent, in violation of 35 U.S.C. § 271(a).

83. Defendant actively instructs, encourages, and/or aids such infringement through various activities, including by training medical professionals to use one or more of the Accused Products in a manner consistent with one or

more claims of the '153 patent, through descriptions on its website and through product documentation.

84. Defendant, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 18 of the '153 patent by contributing to their customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '153 patent. Defendant's customers who make, use, sell, offer for sale, and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 18 of the '153 patent, in violation of 35 U.S.C. § 271(a).

85. Defendant contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '153 patent.

86. The Accused Products are not staple articles of commerce.

87. The Accused Products are not suitable for substantial noninfringing uses.

88. Philips has complied with 35 U.S.C. § 287 for the '153 patent.

89. Philips has been injured by Defendant's infringement of the '153 patent and will suffer irreparable harm unless Defendant is enjoined from infringing the '153 patent.

COUNT V FOR PATENT INFRINGEMENT

Infringement of the '443 Patent

90. Plaintiffs incorporate each of preceding paragraphs 1–89 of this Complaint as if fully set forth and restated herein.

91. In violation of 35 U.S.C. § 271(a), Defendant has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '443 patent, including at least claim 8, by making, using, selling, offering for sale, and/or importing into the United States one or more of the Accused Products.

92. The Polaris Multi-Modality Guidance System is a system for evaluating a vessel of a patient, comprising: a processing system in communication with first and second instruments sized and shaped for introduction into the vessel of the patient (e.g., Polaris processors or software in communication with a COMET pressure guidewire and CONVEY, MACH or RUNWAY Guide Catheters or EXPO or IMPULSE Diagnostic Catheters), the processing unit configured to: obtain pressure measurements from the first and second instruments while the second instrument is moved longitudinally through the vessel of the patient from a first position to a second position while the first instrument is maintained in a fixed longitudinal position with respect to the vessel (e.g., Polaris processors or software obtain pressure measurements while a COMET pressure guidewire is moved longitudinally through the vessel while a CONVEY, MACH or RUNWAY Guide Catheter or EXPO or IMPULSE Diagnostic Catheter remains in a fixed longitudinal position with respect to the vessel); and output a screen display having visual representations of a pressure ratio calculated using the pressure measurements obtained by the first and second instruments on a display in communication with the processing system (e.g., on a monitor display of a Polaris Cart System or Polaris Integrated System), the screen display including: a numerical value of the pressure ratio (e.g., DFR); and a graph of the pressure ratio over a time the second instrument is moved longitudinally through the vessel from the first position to the second position (e.g., a graph related to DFR).

93. Defendant has been on notice of the '443 patent since at least as early as the service of this Complaint. Defendant's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after service of the Complaint, would be with Defendant's knowledge of the '443 patent, knowledge of infringement of the '443 patent, intent to encourage others (e.g., its customers) to infringe the '443 patent through the Accused Products, and knowledge that Defendant's encouraging acts actually result in direct infringement of the '443 patent by Defendant's customers.

94. Defendant had knowledge of the '443 patent or was willfully blind to the patented features of the '443 patent before the filing and service date of this Complaint. Defendant at least had constructive notice of the '443 patent under 35 U.S.C. § 287.

95. Defendant, in violation of 35 U.S.C. § 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 8 of the '443 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '443 patent. Defendant's customers who use, make, sell, offer for sale and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 8 of the '443 patent, in violation of 35 U.S.C. § 271(a).

96. Defendant instructs, actively encourages, and/or aids such infringement through various activities, including by training medical professionals to use one or more of the Accused Products in a manner consistent with one or more claims of the '443 patent, through descriptions on its website and through product documentation.

97. Defendant, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of

equivalents, at least claim 8 of the '443 patent by contributing to their customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '994 patent. Defendant's customers who make, use, sell, offer for sale, and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 8 of the '443 patent, in violation of 35 U.S.C. § 271(a).

98. Defendant contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '443 patent.

99. The Accused Products are not staple articles of commerce.

100. The Accused Products are not suitable for substantial noninfringing uses.

101. Philips has complied with 35 U.S.C. § 287 for the '443 patent.

102. Philips has been injured by Defendant's infringement of the '443 patent and will suffer irreparable harm unless Defendant is enjoined from infringing the '443 patent.

COUNT VI FOR PATENT INFRINGEMENT

Infringement of the '524 Patent

103. Plaintiffs incorporate each of preceding paragraphs 1–102 of this Complaint as if fully set forth and restated herein.

104. In violation of 35 U.S.C. § 271(a), Defendant has infringed, and will continue to infringe literally and/or under the doctrine of equivalents, one or more claims of the '524 patent, including at least claim 11, by making, using, selling,

offering for sale, and/or importing into the United States one or more of the Accused Products.

105. The Polaris Multi-Modality Guidance System is a system of assessing a narrowing in a blood vessel, the system comprising: at least one pressure-sensing probe sized and shaped for positioning within the blood vessel (e.g., a COMET pressure guidewire); and a processor in communication, with the at least one pressure-sensing probe, the processor configured to: receive pressure measurements obtained by the at least one pressure-sensing probe positioned within the blood vessel, the pressure measurements being obtained not during hyperaemia (e.g., a Polaris processor or software receiving pressure measurements while implementing DFR); identify a wave free period corresponding to a time window when a differential flow velocity is minimal or absent (e.g., by implementing the criteria for DFR); and calculate a pressure ratio using the pressure measurements obtained during the wave free period to provide an assessment of a severity of the narrowing in the blood vessel (e.g., by measuring DFR).

106. Defendant has been on notice of the '524 patent since at least as early as the service of this Complaint. Defendant's continued actions of making, using, selling, offering for sale, and/or importing into the United States any of the Accused Products after service of the Complaint, would be with Defendant's knowledge of the '524 patent, knowledge of infringement of the '524 patent, intent to encourage others (e.g., its customers) to infringe the '524 patent through the Accused Products, and knowledge that Defendant's encouraging acts actually result in direct infringement of the '524 patent by Defendant's customers.

107. Defendant had knowledge of the '524 patent or was willfully blind to the patented features of the '524 patent before the filing and service date of this

Complaint. Defendant at least had constructive notice of the '524 patent under 35 U.S.C. § 287.

108. Defendant, in violation of 35 U.S.C. § 271(b), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 11 of the '524 patent by actively inducing others to use, make, sell, offer for sale and/or import one or more of the Accused Products in an infringing manner, knowing such acts would constitute infringement of the '524 patent. Defendant's customers who use, make, sell, offer for sale and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 11 of the '524 patent, in violation of 35 U.S.C. § 271(a).

109. Defendant actively instructs, encourages, and/or aids such infringement through various activities, including by training medical professionals to use one or more of the Accused Products in a manner consistent with one or more claims of the '524 patent, through descriptions on its website and through product documentation.

110. Defendant affixes the following article to certain POLARIS Cart or Integrated Systems to encourage, instruct, aid, and promote its customers' infringement regarding the use of DFR:

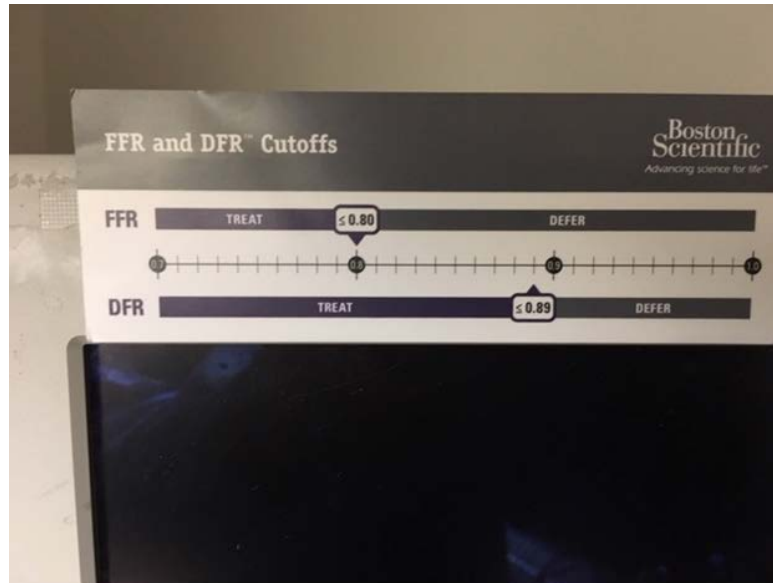


Figure 3: POLARIS DFR Cutoff Graphic

111. Defendant, in violation of 35 U.S.C. § 271(c), has indirectly infringed and continues to indirectly infringe literally and/or under the doctrine of equivalents, at least claim 11 of the '524 patent by contributing to their customers' use, making, selling, offer for sale and/or importing of one or more of the Accused Products in an infringing manner, knowing that those products are especially made or especially adapted to practice one or more of the claims of the '524 patent. Defendant's customers who make, use, sell, offer for sale, and/or import the Accused Products in accordance with Defendant's instructions infringe at least claim 11 of the '524 patent, in violation of 35 U.S.C. § 271(a).

112. Defendant contributes to infringement by providing to its customers the Accused Products or components thereof and instructing them how to assemble, install, make, and/or use the Accused Products, knowing that those products are especially made or adapted for use in infringement of the '524 patent.

113. The Accused Products are not staple articles of commerce.

114. The Accused Products are not suitable for substantial noninfringing uses.

115. Plaintiffs have complied with 35 U.S.C. § 287 for the '524 patent.

116. Plaintiffs have been injured by Defendant's infringement of the '524 patent and will suffer irreparable harm unless Defendant is enjoined from infringing the '524 patent.

DEMAND FOR JURY TRIAL

117. Plaintiffs respectfully request a trial by jury on all claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that this Court enter judgment in their favor on each and every claim set forth above and award them including, but not limited to, the following relief:

A. The entry of judgement that BSC has directly or indirectly infringed the '994, '659, '979, '153, '443, and '524 patents, and continue to do so;

B. The entry of a permanent injunction, enjoining BSC and all persons acting in concert or participation with BSC from further acts of direct and/or indirect infringement of the '994, '659, '979, '153, '443, and '524 patents.

C. Entry of judgment against BSC, awarding Plaintiffs damages adequate to compensate Plaintiffs for BSC's direct and/or indirect infringement of the '994, '659, '979, '153, '443, and '524 patents, including any lost profit and for any continuing or future infringement through the date such judgment is entered, including pre-judgment interest and post-judgment interest, costs, and expenses, as well as an accounting and award of damages against BSC for all future infringing acts occurring after the date such judgment is entered;

D. Entry of judgment as provided by 35 U.S.C. § 285 that this case is exceptional and an award granting Plaintiffs reasonable attorneys' fees, expenses, and costs; and

E. Entry of judgment in favor of Plaintiffs granting any further or additional relief the Court deems just and proper.

Respectfully submitted,

/s/ Karen E. Keller

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